29. The method of claim 28, wherein said reconstituted vaccine contains about $10^{0.0}$ EID_{50} per dose to about $10^{1.0}$ EID_{50} per dose.

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REMARKS

Reconsideration and allowance of the application are respectfully requested in light of the foregoing amendments and the following remarks.

Claims 1 – 16, 18, 19 and 21 - 24 were pending in the application. In an effort to expedite prosecution, claims 1 - 14 and 23 are cancelled herein. (It is applicants' position that the invention is still one that can be *implicitly* recognized as not involving a serial passaging of a vaccine after it has been commercially obtained. However, to avoid debating the issue of "new matter", applicants have instead amended claim 24 (as discussed below) to recite the invention using features *explicitly* set forth in the specification.)

Independent claim 24 has been amended to more succinctly claim the subject invention. Support therefor may be found in the specification at page 5, lines 12 – 13, and page 5, line 21 through page 6, line 6. The Office will note the term "Next" appearing on line 26 of page 5. Claim 24 is also amended to utilize the terms "avirulent" and "IBV", as helpfully suggested by the Office for consistency with independent claim 15.

In addition, claims 15 and 16 have also been amended. Claim 15 is amended to recite that the claimed vaccine is a reconstituted (diluted with suitable neutral media), commercially-available vaccine that has not been approved or indicated for in ovo administration. Support for this amendment may be taken from the specification where indicated for amended claim 24, *supra*. Claim 16 is amended to more precisely set forth the claimed percentage. Support may be found on page 7, line 3 of the specification. (It is applicants' position that claim 16 - and all claims - are read in light of the specification. The skilled artisan could therefore have turned to the specification at the page and line indicated, and thereby determined the

meaning of the term "significantly". However, to expedite prosecution, applicants have removed this latter term which the Office felt was indefinite.)

New claims 25, 26, 27, 28 and 29 are directed to additional embodiments of the invention. Claim 25 is directed to a method of producing an IB vaccine. Support therefor is taken from the specification as regards amended claim 24, *supra*. Claims 26 and 27 mirror pending claims 21 and 22, respectively, but are dependent from new claim 25 instead of claim 19. Likewise, claims 28 and 29 are dependent on pending claim 24.

Entry of the foregoing amendments and new claims is respectfully requested.

Attached hereto is a marked-up version of the changes made to the claims by the amendments set forth above. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Claims 13, 14, 16, 18 and 24 were rejected under 35 U.S.C. §112, second paragraph. The rejection as it pertains to claims 13 and 14 is now rendered moot by the cancellation of those claims. Regarding claims 16 and 24, the rejection should now be obviated as discussed *supra*. The rejection is respectfully traversed as it pertains to claim 18. It is now well accepted practice to utilize terms such as "*substantially* no" to guard against potential infringers who might seek to circumvent the claim by utilizing *de minimis* amounts of virus neutralizing factor. Applicants respectfully request the Office to reconsider and withdraw this rejection for the reasons set forth.

Claims 1 – 14 were rejected under 35 U.S.C. §112, first paragraph. This rejection is now rendered moot by the cancellation of those claims.

Claims 1, 7 – 13, and 23 stand rejected under 35 U.S.C. §102(b) as being anticipated by Wakenell et al.'s article in the American Journal of Vet. Research entitled "*Chicken embryonal vaccination with avian infectious bronchitis virus*". This rejection is also rendered moot by the cancellation of the subject claims.

Claims 2 – 6, 14 - 16, 18, 19, 21, 22, and 24 stand rejected under 35 U.S.C. §103(a) as being obvious over the cited Wakenell et al. article cited above, further in view of Sharma et al., U.S. Patent No. 4,458,630. This rejection, as it relates to non-cancelled claims 15, 16, 18, 19, 21, 22 and 24, is respectfully traversed.

Wakenell et al. do not describe a vaccine which, once obtained from a commercial source and not otherwise approved or indicated for *in ovo* administration, is reconstituted and ready for administration to poultry eggs. Instead, the reference describes a vaccine which is instead derived from a commercial source and then serially passaged to achieve attenuation. In fact, the authors expressly teach away from the present invention by declaring:

"V-IBV [the commercially available vaccine] *was found to be highly pathogenic for embryos, as measured by both hatchability and survival. . . Dilution of V-IBV from* 10^5 EID_{50} *to* 10^2 EID_{50} *did not significantly (P > 0.05) improve either hatchability (48%) or survival (0%)."*

In other words, the authors predicted scant success in fashioning a vaccine as set forth by the present applicants. They ultimately felt that *serial passaging* and not *reconstitution* was the only way to achieve an effective, non-lethal vaccine. This would have no doubt dissuaded the skilled artisan from proceeding in the manner as claimed. There is simply no teaching or hint in the reference that an IB vaccine or method of vaccination, having the claimed characteristics, could be developed.

Sharma et al. does not remedy the shortcomings of the Wakenell et al. article. The secondary reference instead relates broadly to a method of embryonal vaccination in which the *time* and *site* of injection are "critical" (column 3, line 14). Specific reference is made to the use of turkey herpesvirus vaccine (HVT) to protect against Marek's Disease. There appears to be no discussion of whether a commercial vaccine, not otherwise approved or indicated for in ovo administration, can be reconstituted and administered to embryos for protection against *any* poultry disease. Sharma et al. would therefore have provided scant guidance to the skilled

artisan as embodied in the present applicants. Moreover, the reference would not have advanced the Wakenell et al. teachings in the direction as presently claimed.

The present inventors defied the conventional thinking by developing a vaccine in the manner recited. They proceeded in a direction contrary to that which was commonly accepted by the art. They obtained a vaccine which attains a highly acceptable level of hatchability, *i.e.* it is non-lethal to a very large number of embryos, and also protects the hatchlings from IB contagion. They are therefore entitled to patent protection for their discovery.

Additionally, and in particular regarding claims 24, 25 and their progeny, the present applicants have also discovered a different means of producing a vaccine, and a different method of vaccination, than what was taught by the art. There is nothing in either of the cited references to suggest that a vaccine could be produced by formulating it in the manner as set forth in claim 25. Nor is there any teaching to administer the vaccine as recited in claim 24. Instead, Wakenell et al. chose to obtain a commercial vaccine and then weaken it via an elaborate attenuation scheme. They required 20-40 tissue-culture passages before their vaccine was safe to use on chicken embryos! Only then could the vaccine be administered to poultry eggs to achieve the reported results. Sharma et al. felt that criticality lie in the time of vaccination, as well as in the site thereof. Neither would have motivated the person skilled in the art towards what is presently claimed.

Based on the foregoing, it is respectfully submitted that the claimed invention is not obvious in view of the combination of the Wakenell et al. and Sharma et al. references. Withdrawal of the obviousness rejection is therefore respectfully urged.

The application is believed to be in proper condition for allowance, and prompt, favorable action thereon is earnestly solicited. Should Examiner Foley feel that any other point requires consideration, then she is cordially invited to contact the undersigned.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

AMENDED CLAIMS:

15. (Thrice Amended) An in ovo vaccine for protecting chickens from exposure to virulent infectious bronchitis virus, wherein said vaccine [comprises] consists essentially of a solution containing, on a chicken egg basis, a live avirulent strain of infectious bronchitis virus in an immunogenically-effective amount within the range of about $10^{-1.0}$ EID_{50} per egg to about $10^{2.0}$ EID_{50} per egg, wherein said solution is a reconstituted solution of a commercial vaccine against infectious bronchitis which has not been approved or indicated for in ovo administration.

16. (Amended) The vaccine of claim 15, wherein the immunogenically-effective amount is efficacious against subsequent post-hatch exposure of the chicken to virulent infectious bronchitis virus and does not [significantly] decrease the percentage of in ovo vaccinated chicken eggs that hatch upon the expiration of the incubation period below 72%.

24. (Amended) A method of vaccinating a poultry animal against infectious bronchitis (IB), which [comprises] consists essentially of obtaining a commercial vaccine against IB which has not been approved or indicated for in ovo administration and thereafter [directly] reconstituting said vaccine and administering said vaccine in ovo to a member selected from the group consisting of chickens, turkeys, ducks, geese, bantams, quail and pigeons, wherein said reconstituted vaccine contains a live, [nonvirulent] avirulent strain of IB virus (IBV) in a quantity sufficient to confer immunity in an amount within the range of about $10^{-1.0}$ EID_{50} per dose to about $10^{2.0}$ EID_{50} per dose.

NEW CLAIMS:

25. (New) A method of producing a poultry vaccine against infectious bronchitis (IB), which consists essentially of obtaining a commercial vaccine against IB which has not been approved or indicated for in ovo administration, and thereafter

reconstituting said vaccine, wherein said reconstituted vaccine contains a live, avirulent strain of IB virus (IBV) in a quantity sufficient to confer immunity in an amount within the range of about $10^{-1.0}$ EID_{50} per dose to about $10^{2.0}$ EID_{50} per dose.

26. (New) The method of claim 25, wherein said reconstituted vaccine contains about $10^{0.0}$ EID_{50} per dose to about $10^{2.0}$ EID_{50} per dose.

27. (New) The method of claim 26, wherein said reconstituted vaccine contains about $10^{0.0}$ EID_{50} per dose to about $10^{1.0}$ EID_{50} per dose.

28. (New) The method of claim 24, wherein said reconstituted vaccine contains about $10^{0.0}$ EID_{50} per dose to about $10^{2.0}$ EID_{50} per dose.

29. (New) The method of claim 28, wherein said reconstituted vaccine contains about $10^{0.0}$ EID_{50} per dose to about $10^{2.0}$ EID_{50} per dose.